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Dated: August 18, 2009 **Name of Person Certifying:**_____
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Marquez, et al.	) Group Art Unit: 3738
Application No.: 10/811,565	) Examiner: Christopher D. Prone
Filing Date: March 29, 2004	) **Customer Number: 30452**
For: CONTROLLED SEPARATION HEART VALVE FRAME	) Confirmation No.: 1380

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. §41.41

Dear Sir:

This is a reply to the Examiner's Answer dated June 16, 2009. This Reply Brief was to be filed within the two (2) month response period, which ends on Monday, August 17, 2009, but was not able to be filed until just after midnight August 17 due to problems with the Private Pair system or with the connection between the transmitting computer and the Pair system. Something was slowing the rate of transmission and web page loading, and the connection actually failed twice. Consequently, the minor delay was due to unavoidable cause, and Applicants petition under 37 C.F.R. §41.41(c) and 1.136(b) for a one month extension of time. Please charge the fee of $200 under 1.17(g) to Deposit Account 50-1225.

The following responds only to the Examiner's comments on the argument section of the Appeal Brief, and in particular concerning the rejection of claims 1-18 under 35 U.S.C §103(a)

as being obvious over U.S. Patent No. 6,736,845 to Marquez, et al. in combination with U.S. Patent No. 6,696,169 to Klöckner, et al. (English equivalent of WO 00/53356).

Claim 1 specifies a prosthetic heart valve support frame that exhibits a substantially continuous stiffness along the cusps and commissures similar to that resulting from the cusps and commissures being formed integrally. The support member commissures are designed to fracture upon repeated relative movement of the cusps after implantation. Claim 14 requires the support frame be made integrally of a homogeneous material.

Applicants first stated that Marquez, et al. does not disclose the presently claimed support frame (stent) having a substantially continuous stiffness along the cusps and commissures and designed to fracture upon repeated relative movement of the cusps after implantation. Marquez, et al. instead discloses ***flexible*** commissures that permit the separate cusps to pivot with respect to one another. This is not a substantially continuous stiffness.

Examiner Prone answered by emphasizing his reliance on the combination of Marquez, et al. with Klöckner, et al. Of course we recognize that it is the combination of the two references being applied, and in the construct of the Examiner the stent of Marquez, et al. has points between the cusps that fracture, similar to the examples in Klöckner, et al. (albeit in a different field). However, we had pointed out the flexible nature of the commissures of Marquez, et al. because they are dissimilar from the support frame structure of claims 1 and 14, and because the intended flexibility runs counter to a frame having substantially continuous stiffness. Even if fracturable points are added to the stent in Marquez, et al. it still does not have a substantially continuous stiffness. Instead, the combination would be a stent with flexible commissures that eventually fracture. So, it is entirely relevant to examine the structure disclosed in Marquez, et al. because it purportedly provides the claimed heart valve support frame minus the fracturable commissures.

Examiner Prone further transfers not just the fracturable points from Klöckner, et al. to the stent of Marquez, et al., but also contends that the resulting combination "would have a continuous stiffness that will fracture upon movement after implantation." Applicants disagree

with this presumption. Klöckner, et al. pertains to an expanded metal mesh cut so that certain links remain joined at nodes configured as break points. The nodes are described as being "ultrathin" (see Col. 1, line 55 of USPN 6,696,169). Applicants fail to see how such a structure "exhibits a substantially continuous stiffness along the cusps and commissures" with "commissures designed to fracture upon repeated relative movement of the cusps after implantation." Instead, the ultrathin nodes of the metal mesh of Klöckner, et al. would seem to be substantially weaker than the surrounding mesh, and certainly not as stiff. There is no mention of providing break points that withstand "repeated relative movement" before fracture, and a reasonable reading of Klöckner, et al. is that the ultrathin break points fracture rather quickly.

Therefore, the structural combination put forth by the Examiner consists of a heart valve stent frame that has highly flexible commissures supplanted by highly frangible "ultrathin break points." This is not what is claimed.

The Examiner then states that all that is required in claim 1 is a "continuous stiffness which the combination discloses through its materials and configurations not a specific degree of stiffness." To the contrary, claim 1 requires a support frame that exhibits a substantially continuous stiffness along the cusps and commissures similar to that resulting from the cusps and commissures being formed integrally, and commissures each having a point of weakness designed to fracture upon repeated relative movement of the cusps after implantation such that the cusps move substantially independently of each other. Such a substantially continuous stiffness is not the same as ultrathin break points as in Klöckner, et al., which presumably are substantially weaker (and thus less stiff) than the adjacent metal mesh. Applicants assert that the claim language is sufficiently clear to define a particular stiffness without actual quantification of stiffness values or whatever the Examiner implies. The substantially continuous stiffness is that which enables the commissures to fracture only upon repeated relative movement of the cusps after implantation. See paragraph [0032] of the present application for more discussion of the characteristics of the stent stiffness and points of weakness at the commissures. It is also worth noting that the main inventor of the present application and Marquez, et al. is the same person

who understood the difference between the present invention and his previous one.

Next, the Examiner takes issue with the discussion of the respective fields of endeavor. It is a fact that in the Final Office Action the Examiner stated the field of endeavor of Klöckner, et al. was the "same" as Marquez, et al. Since Marquez, et al. is in the area of heart valve fabrication, Applicants reasonably concluded that the Examiner lumped Klöckner, et al. in that field. It is disingenuous to criticize the discussion about field of endeavor in the Appeal Brief by saying that the Examiner "never claimed that Klöckner was in the field of heart valve fabrication."

Later, in the Advisory Action and continuing now, the Examiner restated the relevant field of endeavor as "structural fabrication of metal devices." This characterization is overbroad. The natural consequence of such a broad field is that any metal-working technique may be imputed to an existing heart valve to render obvious a novel construction in that specialized field, which is what we have here. Applicants do not believe that such a broad collection of prior art is warranted.

Another contention in this regard is that the "claims are not even directed at heart valve fabrication because they are only directed at the final product." Apparently this permits the Examiner to borrow from the general field of "metal fabrication." Applicants fail to see how a claim to a heart valve component does not naturally fall into the category of heart valve fabrication. Applicants maintain that the general field of metal fabrication is not *per se* applicable to a claim to a heart valve component. In the present example, the break points provided at nodes in a metal mesh, as in Klöckner, et al. in the paragraph bridging cols. 1 and 2, are designed for:

> The mesh can be filled out or coated with curing or elastomeric polymerizing or dry substances or compounds and thus are useful e.g. as lathing as well as in roofing applications as products having become popular as "lead replacements". Further possible applications include: 1. spacers for cavity claddings, 2. tailored packings for spherical objects and the like, 3. drying grids and filter cages for industrial and domestic purposes, 4. mattings as employed in automotive repair as a replacement for glass-fiber plastics.

The correct inquiry is whether one of skill in the art would look to the teachings of one reference to combine them with those of a second. One of skill in the art here means someone skilled in heart valve fabrication. Such a person would likely already be aware of the concept of frangible break points, even without the "help" of Klöckner, et al. But the question is whether that person would transfer that concept to a stent as in Marquez, et al. Since Marquez, et al. do not teach points of weakness, there is no motivation to look to any secondary reference to find one, let alone a reference (Klöckner, et al.) in the general field of metal fabrication. The only motivation apparent to the Applicants is a hindsight view of the present claims.

Accordingly, Claims 1-18 are allowable over the combination of Marquez, et al. and Klöckner, et al.

Examiner Prone again cites several other old patents that teach breakable metal joints. USPN 2,247,499 pertains to a screw manufacturing technique, and USPN 3,439,917 pertains to a pool ball manufacturing technique. The existence of frangible connections in various unrelated fields provides one of skill in the art with no greater insight prior to the present invention for forming the claimed heart valve support stent. Applicants respectfully find these references, as with Klöckner, et al., to be irrelevant.

Respectfully submitted,

Date: August 17, 2009

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